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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,085	01/08/2004	Ming H. Wu	MEM-0005-P	8184
23413	7590	03/13/2006	EXAMINER	
CANTOR COLBURN, LLP 55 GRIFFIN ROAD SOUTH BLOOMFIELD, CT 06002			MORILLO, JANEL COMBS	
			ART UNIT	PAPER NUMBER
			1742	
DATE MAILED: 03/13/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/755,085

Applicant(s)

WU, MING H.

Examiner

Janelle Combs-Morillo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>082405</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102/103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 4-6, 8-17, 24, 26, 41, 43-53 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schetky et al (US 6,258,182).

Schetky teaches examples within the instant Mo_{eq} range in Table III, alloys 27 ($Mo_{eq}=10.45$), 28 ($Mo_{eq}=9.22$), and 36 ($Mo_{eq}=9.4$). Schetky teaches said alloy has a beta phase (abstract), has linear elastic properties (column 4 line 16), pseudoelastic properties (column 3 line 14), superelastic properties (column 3 lines 27-28), and has a martensitic structure (abstract). Schetky teaches cold working a wire up to 20% reduction (column 3 line 13), but does not mention a reduction in the elastic modulus of $\geq 10\%$ after said cold working (amended claims 1, 3, 28, 39, 41, 47). However, because Schetky teaches examples of a Ti alloy with a Mo_{eq} amount that falls within the instant range, and wherein said alloy exhibits superelastic and pseudoelastic properties and is cold worked substantially as presently claimed, then substantially the same reduction in elastic modulus is held to inherently occur for the alloy taught by Schetky, as in the instant invention. It is held that Schetky anticipates the presently claimed invention.

Alternatively, because Schetky teaches overlapping alloying ranges processed in a substantially similar method, then substantially the same reduction in elastic modulus is expected

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to occur for the alloy taught by Schetky, as in the instant invention. It is held that Schetky has created a prima facie case of obviousness of the presently claimed invention. See MPEP 2144.05. In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

Concerning claim 2, the alloy taught by Schetky meets the presently claimed relationship, as determined by the instant the equation for said Mo_{eq} in claim 2 (see above reference to examples 27, 28, and 36).

Concerning the process limitations of dependent claims 4, 41, 43-47, Schetky teaches cold working a wire up to 20% reduction, further heat treatment including solution heat treating 780-880°C (column 12 line 60), and aging at 200-400°C (column 11 lines 18) for 0.1-10,000 min (see Fig. 7), which substantially overlaps the presently claimed heat treatment time and temperatures. Said solution heat treatment temperature taught by Schetky overlaps heating above the beta transus.

Concerning claims 5, 6, 8, 9, 50, 51, because Schetky teaches a substantially overlapping alloy composition, processed in a substantially similar method, then substantially the same properties, such as elastic recovery are inherently present.

Schetky teaches ex. 28 exhibits a 3% elastic spring back (Table 3) when loaded to 4% strain at room temperature (column 3 lines 19-21), which meets the elastic recovery limitation of claims 6 and 51. Concerning the elastic recovery (cl. 5, 51) and elastic modulus (cl. 8, 9) limitations, because Schetky teaches a substantially overlapping alloy composition, processed in

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a substantially similar method, then substantially the same properties, such as elastic recovery and elastic modulus are inherently present.

Concerning claims 10, 26, 41, 49, Schetky teaches said alloy has a beta phase (abstract), has linear elastic properties (column 4 line 16), and has pseudoelastic properties (column 3 line 14) and superelastic properties (column 3 lines 27-28), and has a martensitic structure (abstract).

Concerning claims 11-17, 52, 53, which mention said Ti-Mo-Al alloy is in the form of a medical device, Schetky teaches said alloy has excellent biocompatibility and is useful for a variety of medical uses, including: orthodontic arch wires, a stent, catheter, dental implants, bone staples, eyeglass frames (column 3 lines 22-27).

Concerning claims 13, 14, 24, which mention said Ti-Mo-Al alloy is welded, Schetky teaches said alloy exhibits superior weldability (column 2 line 59, column 5 line 15), when said alloy is formed and welded (column 5 line 15).

Concerning claim 47, 48, Schetky teaches said alloy is formed into a wire, for example, 0.4 mm in diameter (column 9 lines 15-16).

Because the prior art teaches examples within the presently claimed alloying ranges, as well as a substantially identical product by process, it is held that Schetky anticipates or has created a prima facie case of obviousness of the presently claimed invention.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3, 25, 28-30, 34-37, 39, 40, 42, 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schetky et al (US 6,258,182).

Schetky is discussed in paragraphs above. Schetky teaches a beta phase titanium alloy preferably comprising: 10-12% Mo, 2.8-4% Al, 0-2% Cr, and 0-4% Nb (see abstract), which overlaps or touches the boundary of the composition in instant claim 3. While the preferred range taught by Schetky does not overlap the alloys of independent claims 28 and 39, the alloys of claims 28 and 39 fall within the scope of the limits of Mo, Al, Cr, V, and Nb listed in the examples of Schetky in Table III columns 7 and 8, wherein said examples encompass: 8.4-12% Mo, 2.3-3.7% Al, 0-1.8% Cr, 0-1.8% V, 0-3.8% Nb. Overlapping ranges have been held to be a prima facie case of obviousness, see MPEP § 2144.05. It would have been obvious to one of ordinary skill in the art to select any portion of the range, including the claimed range, from the broader range disclosed in the prior art, because the prior art finds that said composition in the entire disclosed range has a suitable utility. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

Concerning claims 25, 34, 35, which mention said Ti-Mo-Al alloy is welded or brazed, Schetky teaches said alloy exhibits superior weldability (column 2 line 59, column 5 line 15).

Concerning claims 29, 30, 40, as stated in paragraphs above, Schetky teaches said Ti alloy can be made into a variety of medical devices.

Concerning claims 36 and 37, Schetky teaches said alloy has a beta phase (abstract), has linear elastic properties (column 4 line 16), and has pseudoelastic properties (column 3 line 14) and superelastic properties (column 3 lines 27-28), and has a martensitic structure (abstract).

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Concerning claim 42, though Schetky does not teach a product produced by solution heating below the beta transus, the temperature range of solution heating given by Schetky of 780-880°C (column 12 line 60), overlaps the solution heat treatment range given in the instant specification typical of below the transus temperature (see [0056]).

Concerning claims 54, though Schetky does not specify forming said alloy into a file or drill for dental applications, because of the excellent biocompatibility of the Ti-Mo-Al alloy taught by Schetky, it is held to be useful for a variety of medical and dental purposes, such as a file or drill.

5. Claims 18-23, 31-33, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schetky as applied to claims above, and further in view of Aizawa et al (US 5,658,207).

Schetky does not mention said Ti-Mo-Al alloy is formed into a portion of a golf club. However, Aizawa teaches that titanium alloys can be formed into golf club heads (column 1 line 10), and wherein said golf club head can be secured by welding or press fitting (column 6 lines 54-55). It would have been obvious to one of ordinary skill in the art to form the Ti alloy taught by Schetky into a golf club head taught by Aizawa, because Schetky teaches said alloy has excellent tensile strength properties (column 9 line 20).

6. Claims 27 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schetky as applied to claims above, and further in view of Davidson (US 6,238,491).

Schetky does not teach the application of a polymer coating to the instant Ti-Mo-Al alloy. However, Davidson teaches that similar Ti alloys used for medical implants can be coated in order to further improve biocompatibility, wherein said coating can be a polymer (column 13 lines 40-46). It would have been obvious to one of ordinary skill in the art to coat the Ti-Mo-Al

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alloy medical device taught by Schetky with a polymer coating as taught by Davidson, because Davidson teaches said coating improves biocompatibility (column 14 lines 40-46).

Response to Amendment/Arguments

7. In the response filed on December 15, 2005 applicant amended claims 1, 3, 4, 28, 39, 41-47 and submitted various arguments traversing the rejections of record. The examiner agrees that no new matter has been added.

8. Applicant's argument that the present invention is allowable over the prior art of record because Schetky does not teach cold working in order to reduce the elastic modulus has not been found persuasive. Schetky is silent on the elastic modulus of said alloy. But because Schetky teaches substantially the same alloy processed in substantially the same method, then substantially the same results are held to inherently occur. Once a reference teaching product appearing to be substantially identical is made the basis of a rejection, and the examiner presents evidence or reasoning tending to show inherency, the burden shifts to the applicant to show an unobvious difference. "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)), see MPEP 2112. In re Schreiber, 128 F.3d 1473, 1478, 44 USPQ2d 1429, 1432 (Fed.Cir.1997). Applicant has not clearly shown an unobvious difference between the instant invention and the prior art's product. Though Applicant

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argues that unexpected results have clearly been shown with respect to Schetky, it is unclear how the pseudo-elastic strain recovery of Schetky relates to the reduction of the elastic modulus.

9. With respect to the evidence that cold working an alloy with the instant alloying ranges/molybdenum equivalent is critical (and therefore exhibits unexpected results), applicant has not clearly shown a nexus between the merits of the claimed invention and the evidence of secondary considerations (for MPEP 716.01b, MPEP 716.01-02 in general).

10. Applicant's argument that the present invention is allowable over the prior art of record because Schetky does not teach examples within the claimed ranges/Schetky teaches against the present invention has not been found persuasive. Patents are relevant as prior art for all they contain, and nonpreferred embodiments constitute prior art, MPEP 2123. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art reference taught a printed circuit material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use, but that epoxy impregnated circuit boards have "relatively acceptable dimensional stability" and "some degree of flexibility," but are inferior to circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that applicant's argument that the reference teaches away

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from using epoxy was insufficient to overcome the rejection since "Gurley asserted no discovery beyond what was known in the art." 27 F.3d at 554, 31 USPQ2d at 1132.).

Though Schetky teaches preferred embodiments with an amount of Mo that touches the boundary or is higher than the claimed amount of Mo, Schetky also teaches examples with Mo contents within the instant range can still exhibit beneficial elastic spring back and a small amount of shape memory recovery (Table III). Though Schetky teaches the elastic spring back for alloys with lower Mo is expected to be less than the elastic spring back for alloys with higher, it is unclear how/if Applicant's alloy exhibits unexpected results with respect to the lower Mo alloys taught by the prior art.

Applicant has not clearly shown specific unexpected results with respect to the overlapping composition taught by the prior art or criticality of the instant claimed range- such as unexpected strain recovery or shape memory recovery, etc. (wherein said results must be fully commensurate in scope with the instantly claimed ranges, see MPEP 716.02 d).

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-6, 8-55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 of copending Application No. 10/609003. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of US'003 are also drawn to a composition with 8-10% Mo, 2.8-6% Al, up to 2% V, up to 4% Nb, balance Ti; wherein said alloy exhibits an elastic recovery substantially as presently claimed (see US'003 at claims 3-10), is produced by solution heating, cold working, cooling in air, aging 350-550°C (US'003 at cl. 2, 11, 12). The Mo_{eq} of said alloy taught by the alloy of claims of US'003 meets the Mo_{eq} given in instant claims 1, 2, 41, 47.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 1-6, 8-55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-49 of copending Application No. 10/755034. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of US'034 are drawn to an overlapping alloy composition with 8-10% Mo, 2.8-6% Al, up to 2% V, up to 4% Nb, balance Ti (US'034 at cl. 4), wherein said alloy exhibits an elastic recovery substantially as presently claimed (see US'034 at claims 10-23), is produced an identical process of solution heating, cold working, cooling in air, aging 350-550°C (US'003 at cl. 6, 17, 31). The Mo_{eq} of said alloy taught by the alloy of claims 1 and 3 of US'034 meets the Mo_{eq} given in instant claims 1, 2, 41, 47.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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14. Claims 1-6, 8-55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-20, 23, 24 of copending Application No. 10/869359. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of US'359 are drawn to an overlapping alloy composition with 8-10% Mo, 2.8-6% Al, up to 2% V, up to 4% Nb, balance Ti (US'359 at cl. 17), wherein said alloy is held to inherently exhibit an elastic recovery substantially as presently claimed, and said alloy product is produced a process of heat treating and cold working (US'359 at cl. 15, 18). The Mo_{eq} of said alloy taught by the alloy of claims of US'359 meets the Mo_{eq} given in instant claims 1, 2, 41, 47.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 1-6, 8-55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25, 39-53 of copending Application No. 10/609004. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of US'004 are drawn to an overlapping alloy composition with 8-10% Mo, 2.8-6% Al, up to 2% V, up to 4% Nb, balance Ti (US'004 at cl. 1), wherein said alloy exhibits an elastic recovery substantially as presently claimed (see US'004 at claims 3-7), is produced an identical process of solution heating, cold working, cooling in air, aging 350-550°C (US'004 at cl. 40-44). The Mo_{eq} of said alloy taught by the alloy of claims of US'004 meets the Mo_{eq} given in instant claims 1, 2, 41, 47.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janelle Combs-Morillo whose telephone number is (571) 272-1240. The examiner can normally be reached on 8:30 am- 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King can be reached on (571) 272-1244. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JCM 
March 6, 2006


GEORGE WYSZOMIERSKI
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